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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,432

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Alan Murray

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,432	Applicant(s) MURRAY ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-12, 15-17, 19, 33-40, 42-47, 50 and 51 is/are allowed.
- 6) ☒ Claim(s) 13, 14, 18, 20-32, 41, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 22 January 2009, is acknowledged. Claims 2, 3, 4, 5, 6, 7, 8, 10, 13, 14, 16, 17, 18, 19, 20, 22, 24, 27, 29, 30 and 41 have been amended. Claim 52 has been canceled.
2. Claims 1-51 are pending and under consideration.

Rejections/Objections Moot or Withdrawn

3. The rejection of claim 52 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of antibody which binds to unknown regions, is moot in light of the cancellation of the claim.
4. The objection to claim 10 is withdrawn in light of the amendment of the claim.
5. The objection to claim 27 is withdrawn in light of the amendment of the claim.
6. The objection to claim 6 under 37 CFR 1.75 as being a substantial duplicate of claim 1, is withdrawn in light of the amendment of the claim to restrict the claimed polypeptide as being obtained from a bacterium while claim 1 makes no restriction of the source of the polypeptide.
7. The objection to claim 7 under 37 CFR 1.75 as being a substantial duplicate of claim 1, is withdrawn in light of the amendment of the claim to restrict the claimed polypeptide as being obtained from *M. avium* subspecies *paratuberculosis* while claim 1 makes no restriction of the source of the polypeptide.
8. The objection to claim 8 under 37 CFR 1.75 as being a substantial duplicate of claim 1, is withdrawn in light of the amendment of the claim to restrict the claimed polypeptide as being obtained from a heterologous host transformed with a polynucleotide which encodes said polypeptide, while claim 1 makes no restriction of the source of the polypeptide.

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9. The objection to claim 9 under 37 CFR 1.75 as being a substantial duplicate of claim 1, is withdrawn in light of the amendment of the claim to restrict the claimed polypeptide as being obtained from a specific bacterial heterologous host, i.e., *E. coli*, transformed with a polynucleotide which encodes said polypeptide, while claim 1 makes no restriction of the source of the polypeptide.

10. The objection to claim 16 under 37 CFR 1.75 as being a substantial duplicate of claim 1, is withdrawn in light of the amendment of the claims to add one or more acceptable diluents, carriers, excipients, or adjuvants to the composition.

11. The objection to claim 17 under 37 CFR 1.75 as being a substantial duplicate of claim 11, is withdrawn in light of the amendment of the claims to add one or more acceptable diluents, carriers, excipients, or adjuvants to the composition.

12. The objection to claim 19 under 37 CFR 1.75 as being a substantial duplicate of claim 14, is withdrawn in light of the amendment of the claims to add one or more acceptable diluents, carriers, excipients, or adjuvants to the composition.

13. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for "the sequence", is withdrawn in light of the amendment of the claim.

14. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite for "the sequence", is withdrawn in light of the amendment of the claim.

15. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "the sequence", is withdrawn in light of the amendment of the claim.

16. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "the sequence", is withdrawn in light of the amendment of the claim.

17.

Rejections Maintained

18. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, at least one embodiment of claim 13 is drawn to a primer capable of amplifying a polynucleotide which encodes any of the listed sequences. The recitation of the polynucleotide permits any number of unknown regions on either end of the region which actually encodes the polypeptide sequences. Thus it remains unclear how one identifies a primer capable of amplifying a polynucleotide which contains the required sequences.

19. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of antibody which binds to unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, the claim is drawn to an antibody capable of binding a polypeptide as defined in claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4 % different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids and the claimed antibody may bind to these unknown regions. Therefore, it remains unclear how one identifies what antibodies are encompassed by the instant claim.

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20. The rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, at least one embodiment of claim 18 is drawn to a primer capable of amplifying a polynucleotide which encodes any of the listed sequences of claim 5. The recitation of the polynucleotide permits any number of unknown regions on either end of the region which actually encodes the polypeptide sequences. Thus it remains unclear how one identifies a primer capable of amplifying a polynucleotide which contains the required sequences.

21. The rejection of claims 20-23, 29 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of immune response, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, the claim is drawn to an antibody capable of binding a polypeptide as defined in claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4 % different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids and the claimed antibody may bind to these unknown regions. Therefore, it remains unclear how one identifies what antibodies are encompassed by the instant claim and thus, how one distinguishes between detecting John's Disease and antibodies which bind to the unknown regions.

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22. The rejection of claims 24-26 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, the claim is drawn to an antibody capable of binding a polypeptide as defined in claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4 % different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids and the claimed antibody may bind to these unknown regions. Therefore, it remains unclear how one identifies what antibodies are encompassed by the instant claim and thus, how one distinguishes between detecting John's Disease and antibodies which bind to the unknown regions.

In addition, because of the recitation of "either"....."or with a composition", the first antibody composition is "a purified or isolated antibody capable of binding a polypeptide". This recitation contains no restriction of the actual binding characteristics. Therefore, it is unclear how one detects John's Disease using such a nonspecific antibody.

23. The rejection of claim 27 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, at least one embodiment of claim 27 is drawn to a primer capable of amplifying a polynucleotide which encodes a polypeptide which

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consists of a sequence of claim 4. At least one embodiment of claim 4 is a polypeptide consisting of an amino acid sequence which is at least 4% different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids, with the encoding polynucleotide permitting any number of unknown regions on either end of the region which actually encodes the polypeptide sequences. Thus it remains unclear how one identifies a primer capable of amplifying a polynucleotide which contains the required sequences and thereby detect Johnne's Disease.

24. The rejection of claims 30-32 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, at least one embodiment of claim 30 is drawn to a polynucleotide capable of binding to a polynucleotide which encodes a polypeptide which consists of a sequence of claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4% different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids, with the encoding polynucleotide permitting any number of unknown regions on either end of the region which actually encodes the polypeptide sequences. Thus it remains unclear how one identifies a polynucleotide capable of binding to a polynucleotide which contains the required sequences and thereby detect Johnne's Disease.

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25. The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of antibody which binds to unknown regions, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, the claim is drawn to an antibody capable of binding a polypeptide as defined in claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4 % different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids and the claimed antibody may bind to these unknown regions. Therefor, it remains unclear how one identifies what antibodies are encompassed by the instant claim.

26. The rejection of claim 49 under 35 U.S.C. 112, second paragraph, as being indefinite for claimed invention, is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claim, but does not find it persuasive. As newly amended, the claim is drawn to a method which utilizes an antibody capable of binding a polypeptide as defined in claim 5. At least one embodiment of claim 5 is a polypeptide consisting of an amino acid sequence which is at least 4 % different from SEQ ID NO:1 or at least 4% different from the sequence of amino acids 20-235 of SEQ ID NO:1. Thus, the unknown regions of the first embodiment may be up to 9 amino acids and the second embodiment, up to 8 amino acids and the claimed antibody may bind to these unknown regions. Therefor, it remains unclear how one identifies what antibodies

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are encompassed by the instant claim and thus, how one distinguishes between detecting John's Disease and antibodies which bind to the unknown regions.

Conclusion

27. Claims 13, 14, 18, 20-32, 41, 48 and 49 are finally rejected.

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 10, 2009